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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0945-0003-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for revision of the approved information collection assigned OMB control number 0945-0003, scheduled to expire on January 1, 2017. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff,

Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0945-0003-30D for reference.

Proposed Project: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164

Abstract: This revision does not change any requirements of the HIPAA Privacy, Security, and Breach Notification Rules. Among other updates summarized below, the ICR requests to rename the information collection and incorporate into it the substance of two other information collections (#0945-0004, set to expire on May 31, 2016; and #0945-0001, expiring on September 30, 2016), which then would be discontinued. The ICR addresses the burden on regulated entities for compliance with the information collection requirements of the HIPAA Privacy, Security, and Breach Notification Rules; the voluntary burden on members of the public for obtaining information from covered entities regarding breaches of their protected health information; and the information collection burden on the Office for Civil Rights (OCR) associated with administering aspects of the HIPAA Breach Notification program. Combining the three existing information collections identified above will allow the regulated community, the public, and OCR to more easily view and track the estimated burdens associated with the HIPAA Rules that are administered and enforced by OCR. In addition to combining the ICRs, the

proposed updates take into account our experience administering the Rules to more accurately reflect the burdens of compliance with the applicable regulatory requirements; remove the estimated burden of initial compliance with the Omnibus HIPAA Final Rule, because we are well past the compliance dates; and incorporate increases in wages for the job categories that we expect to be involved in compliance activities.

Estimated Annualized Burden Table

Section	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
160.204	Process for Requesting Exception Determinations (states or persons)	1	1	16	16
164.308	Risk Analysis - Documentation	1,700,000	1	10	17,000,000
164.308	Information System Activity Review – Documentation	1,700,000	12	.75	15,300,000
164.308	Security Reminders – Periodic Updates	1,700,000	12	1	20,400,000
164.308	Security Incidents (other than breaches) – Documentation	1,700,000	52	5	442,000,000
164.308	Contingency Plan – Testing and Revision	1,700,000	1	8	13,600,000
164.308	Contingency Plan – Criticality Analysis	1,700,000	1	4	6,800,000

164.310	Maintenance Records	1,700,000	12	6	122,400,000
164.314	Security Incidents – Business Associate reporting of incidents (other than breach) to Covered Entities	1,000,000	12	20	240,000,000
164.316	Documentation – Review and Update	1,700,000	1	6	10,200,000
164.404	Individual Notice—Written and E-mail Notice (drafting)	58,481	1	.5	29,240
164.404	Individual Notice—Written and E-mail Notice (preparing and documenting notification)	58,481	1	.5	29,240
164.404	Individual Notice—Written and E-mail Notice (processing and sending)	58,481	353	.008	165,150
164.404	Individual Notice—Substitute Notice (posting or publishing)	2,746	1	1	2,746
164.404	Individual Notice—Substitute Notice (staffing toll-free number)	2,746	1	5.75	15,789
164.404	Individual Notice—Substitute Notice (individuals’	11,326,440	1	.125	1,415,805

	voluntary burden to call toll-free number for information)				
164.406	Media Notice	267	1	1.25	333
164.408	Notice to Secretary (notice for breaches affecting 500 or more individuals)	267	1	1.25	333
164.408	Notice to Secretary (notice for breaches affecting fewer than 500 individuals)	58,215	1	1	58,215
164.414	500 or More Affected Individuals (investigating and documenting breach)	267	1	50	13,350
164.414	Less than 500 Affected Individuals (investigating and documenting breach)	2,479 (breaches affecting 10-499 individuals)	1	8	19,832
		55,736 (breaches affecting <10 individuals)	1	4	222,944
164.504	Uses and Disclosures – Organizational Requirements	700,000	1	5/60	58,333
164.508	Uses and Disclosures for Which Individual authorization is required	700,000	1	1	700,000

164.512	Uses and Disclosures for Research Purposes	113,524	1	5/60	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by paper mail)	100,000,000	1	0.25 minutes [1 hour per 240 notices]	416,667
164.520	Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by electronic mail)	100,000,000	1	0.167 minutes [1 hour per 360 notices]	278,333
164.520	Notice of Privacy Practices for Protected Health Information (health care providers – dissemination and acknowledgement)	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information	20,000	1	3/60	1,000
164.524	Access of Individuals to Protected Health Information (disclosures)	200,000	1	3/60	10,000
164.526	Amendment of Protected Health	150,000	1	5/60	12,500

	Information (requests)				
164.526	Amendment of Protected Health Information (denials)	50,000	1	5/60	4,166
164.528	Accounting for Disclosures of Protected Health Information	5,000	1	3/60	250
Total					921,813,702

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